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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,827	07/28/2006	Naoaki Yamasaki	1830.1025	2378

21171 7590 01/19/2011

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EXAMINER	
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ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
01/19/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,827	YAMASAKI ET AL.	
	Examiner	Art Unit	
	Nathan W. Schlientz	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-12 are pending in the present application and examined herein on the merits for patentability. No claim is allowed at this time.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Obae et al. (WO 02/02643; the English-language equivalent US 2004/0053887 is referred to herein) in view of Yaginuma (JP 01-272643; JP 02-084401; and JP 03-264537), Kennedy et al. (Journal of the European Ceramic Society, 1997), and Ek et al. (US 5,607,695).

Determination of the scope and content of the prior art

(MPEP 2141.01)

Obae et al. teach cellulose powder having an especially excellent balance among moldability, fluidity and disintegrating property, wherein the cellulose powder has an average particle size of 20-250 μm, and an angle of repose of 55° or less (Abstract). Obae et al. teach natural cellulosic material, such as a vegetable fibrous material derived from a natural material containing cellulose, such as wood, bamboo, cotton, ramie or the like, and is preferably a material having a crystalline structure of cellulose I type ([0061]). Conditions for obtaining the cellulose dispersion having an average polymerization degree of 150-450 are, for example, carrying out the hydrolysis under mild conditions in a 0.1-4N aqueous hydrochloric acid solution at 20-60 ℃ ([0062]). Obae et al. further provide examples wherein the average particle size is 30-105 μm, the angle of repose is 35-44°, the specific surface area (nitrogen) is 1.4-2.4 m^2/g ([0201], Table 3 on pg. 18), the hardness is 171-281 N, and the disintegration time is 4-72 sec ([0202], Table 2 on pg. 19). Also, the instant specification states that Obae et al. describes a cellulose powder according to Comparative Examples 2 and 3 (pg. 7, ln. 13-23; and pg. 19, ln. 24); and Comparative Examples 2 and 3 describe cellulosic powder with type I crystalline form cellulose, specific surface area of 1.5 and 1.7 m2/g, secondary aggregate structure, and 45 and 38 μm average particle size (Table 1). Obae et al. further teach a molded product comprising the cellulose powder and an active ingredient ([0035]-[0038] and [0081]-[0083]).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Obae et al. do not explicitly disclose the pore volume within the cellulosic particle of 0.265 cm^3/g to 2.625 cm^3/g, as instantly claimed. However, Yaginuma teaches porous cellulose particles wherein the particles comprise type I crystal form and a pore volume of 0.3-1.2 cm^3/g (Abstracts). The cellulose powder of Obae et al. is prepared in a very similar manner as the porous cellulose particles of Yaginuma, comprising mixing commercial pulp with aqueous HCl and stirring at elevated temperature for a certain amount of time, followed by washing, neutralizing and filtering, then dispersing to a certain solids content and then spray drying (Comparative Examples 2, 3, 6 and 7 of the instant specification). The variables that change from each of Comparative Examples 2, 3, 6 and 7 are the concentration of HCl, temperature and duration of stirring, and the solids content prior to spray drying. It's clear from Obae et al. and Yaginuma that these changes in variables can affect the physical properties of the resulting porous cellulose particles, such as pore volume, specific surface area, average particle size, etc.

Obae et al. also do not explicitly disclose molded products comprising their porous cellulose particles and a poorly water-soluble active ingredient, sublimable active ingredient, an active ingredient that is liquid or semisolid at normal temperatures, or an active ingredient that has been finely pulverized to a particle size of 40 μm or less, or 10 micron or less, as instantly claimed. However, Yaginuma teaches that the porous cellulose particle is suitable as an adsorptive carrier for insoluble fine particle component of foods or pharmaceuticals (Abstract of JP '643); suitable for drug

absorption carriers (Abstract of JP '401); as well as absorbing a drug to the particle by sublimation (Abstract of JP '537). Further, Ek et al. teach porous cellulose particles wherein a bioactive substance or bioactive substances in a solid, liquid, or semisolid form, preferably as a solid, solution, suspension, emulsion, oil, super critical fluid or melt, could be absorbed, precipitated or sublimized into the porous structure of the cellulose matrices (col. 4, ln. 15-20). With regard to the particle size of the active ingredient, in the absence of evidence to the contrary, one of ordinary skill in the art would readily be able to determine the necessary particle size of the active ingredient to be effectively carrier by the porous cellulose particles.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of the invention to alter through routine experimentation the concentration of HCl, temperature and duration of stirring, and the solids content prior to spray drying in order to obtain porous cellulose particles according to Obae et al., wherein the particles comprise a pore volume of 0.3-1.2 cm^3/g, according to Yaginuma. One of ordinary skill in the art would have been motivated to obtain a large pore volume, such as taught by Yaginuma, in order to increase compaction strength, as reasonably taught by Kennedy et al. (Abstract; and pg. 137, left column). It would have also been *prima facie* obvious for one of ordinary skill in the art to use the porous cellulose particles to carry a pharmaceutical active agent that is solid, semisolid, liquid, poorly water-soluble, and/or sublimable, as reasonably taught by Yaginuma and Ek et al.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments filed 21 October 2010 have been fully considered but they are not persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues on page 5 that the cellulose powders of Obae et al. have poor flowability and an angle of repose that is too high. However, the examiner respectfully argues that flowability is a feature that is not currently claimed; and Ex. 4 and Comparative Ex. 2 of Obae et al. each have an angle of repose of 44°, and Comparative Ex. 4 and 9 have angle of repose of 35° and 43°, respectively. Applicant further argues that the Obae et al. cellulose powders lack the intentionally-formed pores that are formed by the instant invention. However, the examiner respectfully argues that according to the instant specification the cellulose powders of Obae et al. have pore volumes of 0.24-0.245 cm^3/g. As noted above, it would have been *prima facie* obvious for one of ordinary skill in the art to increase the pore volume through routine

experimentation in order to increase compaction strength, as reasonably taught by Kennedy et al.

Applicant argues that the porous cellulose particles of Yaginuma do not have the claimed secondary aggregate structure. However, as noted by applicant, the cellulose particles of Obae et al. do have a secondary aggregate structure formed by aggregation of primary cellulose particles (Table submitted with applicant's Remarks). Yaginuma was cited to show that one of ordinary skill in the art would be able to change the physical properties of the cellulose particles of Obae et al. through routine experimentation, such as altering the concentration of HCl, temperature and duration of stirring, and the solids content prior to spray drying.

Applicant further argues on page 6 that the particle shape of the cellulose particle group having a larger average particle size affects the pore volume within the particle at the time of drying. However, the shape of the cellulose particle group having a larger average particle size is not currently claimed. It's also noted that the difference in average particle size between the two or more groups of primary cellulose particles is not instantly claimed (i.e., the difference shown in applicant's Remarks, 29-80 μm, is not a required limitation, such that the difference could be a couple of μm).

Applicant also argues on page 7 that Obae et al. cannot achieve the claimed pore volume merely by adjusting the hydrolysis conditions described by Obae and so on. However, the arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an

appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. See MPEP 716.01(c)(II).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is (571)272-9924. The examiner can normally be reached on 9:00 AM to 5:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWS

/John Pak/
Primary Examiner, Art Unit 1616